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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624,915

07/22/2003

D. Russell Pflueger

QMI-3077

7109

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7590

03/11/2008

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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

03/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/624,915	<b>Applicant(s)</b> PFLUEGER ET AL.	
	<b>Examiner</b> NIHIR PATEL	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02.11.2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 52-55, 66-68, 70-78, 80-83 and 85-107 is/are pending in the application.
- 4a) Of the above claim(s) 95 and 96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-55, 66-68, 70-78, 80-83, 85-94 and 97-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Response to Arguments***

1. Applicant's arguments filed on February 11<sup>th</sup>, 2008, with respect to claims 52, 82 and 93 have been fully considered and are persuasive. The previous rejection(s) of the office action dated December 11<sup>th</sup>, 2007 has been withdrawn due to the newly found reference to Nelson et al.

Claims 1-51, 56-65, 69, 79 and 84 are canceled and claims 52-55, 66-68, 70-78, 80-83 and 85-107.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims **82, 83, 85-94, 97 and 99-101** are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. (US 7,188,627).

4. **As to claim 82**, Nelson teaches an apparatus that comprises an appliance **52 (see figures 7A and 7B; column 10 lines 10-20)** comprising two elongated curved elements made of biocompatible metal (**see figures 7A and 7B; column 10 lines 45-55**), each of the curved elements having a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle (**see figures 7A and 7B**), the two elements being coupled together at respective first and second ends (**see figures**

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**7A and 7B**), and being spaced apart from each other between the first and second ends to define an open interior space therebetween (**see figures 7A and 7B**), the appliance being sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall and when so placed being effective in treating sleep apnea, wherein the appliance includes only two elongated curved elements, each of the curved elements has a curved length extending from the first end to the second end, and the first end and the second end define a gap therebetween extending outwardly away from the first and second curved elements having a gap length which is reduced relative to the curved length of each of the curved elements (**see figure 7B; reference character 56 defines the a gap**).

5. **As to claim 83**, Nelson teaches an apparatus wherein the substantially circular dimension between the first end and the second ends extends through at least 180 degrees of a circle (**see figures 7A and 7B**).

6. **As to claim 85**, Nelson teaches an apparatus wherein each if the two elongated elements comprises a resilient wire (**see figures 7A and 7B; column 10 lines 10-20**).

7. **As to claim 86**, Nelson teaches an apparatus wherein the appliance comprises a C-shaped structure (**see figures 7A and 7B; the loop in figures 7A and 7B is defined as C-shaped structure**).

8. **As to claim 87**, Nelson teaches an apparatus wherein the two elements are portions of the same structure (**see figures 7A and 7B**).

9. **As to claim 88**, Nelson teaches an apparatus wherein the appliance has a lateral dimension defined by the distance between the first and second ends and a maximum

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longitudinal dimension perpendicular to the lateral dimension which is less than the lateral dimension **(see figures 7A and 7B)**.

10. **As to claim 89**, Nelson teaches an apparatus wherein the appliance has a concave loop configuration when the appliance is so placed in the oropharyngeal region **(see figures 7A and 7B)**.

11. **As to claim 90**, Nelson teaches an apparatus wherein the appliance is sized and structured to be placed below a soft palate of a human or animal **(see column 6 lines 60-67; column 7 lines 1-10; and column 10 lines 10-20)**.

12. **As to claim 91**, Nelson teaches an apparatus wherein the appliance is made of an elastic spring memory material **(see column 10 lines 45-55)**.

13. **As to claim 92**, Nelson teaches an apparatus wherein the appliance is made of nitinol **(see column 10 lines 45-55)**.

14. **As to claim 93**, Nelson teaches an apparatus that comprises an appliance **52 (see figures 7A and 7B; column 10 lines 10-20)** comprising an elongated loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions **(see figures 7A and 7B)**, the appliance being sized for introduction into an oropharyngeal region of a human or animal and deployable in a C shaped deployed configuration in which at least one of the elongated elements extends generally laterally across the posterior wall and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region **(see figures 7A and 7B; the loop in figures 7A and 7B is defined as C-shaped structure)**.

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15. As to **claim 94**, Nelson teaches an apparatus wherein the appliance defines an open interior space between the spaced apart elongated elements (**see figure 7B; reference character 56 defines the gap**).

16. As to **claim 97**, Nelson teaches an apparatus wherein the substantially C shaped configuration, the first and second end portions define a gap therebetween (**see figure 7B; the loop in figures 7A and 7B is defined as C-shaped structure**).

17. As to **claim 99**, Nelson teaches an apparatus wherein the appliance is biocompatible metal (**see column 10 lines 45-55**).

18. As to **claim 100**, Nelson teaches an apparatus that comprises an appliance comprising a single continuous loop comprising first and second rounded end portions and two spaced apart elongated elements extending between the first and second end portions such that the loop defines an open interior space between the spaced apart elongated elements **52 (see figures 7A and 7B; column 10 lines 10-20)**, the appliance being sized for introduction into an oropharyngeal region of a human or animal and deployable in a C shaped deployed configuration in which the elongated elements extending generally laterally across the posterior wall and the first and second end portions bearing against and providing an opening force against the lateral walls of the oropharyngeal region (**see figures 7A and 7B; the loop in figures 7A and 7B is defined as C-shaped structure**).

19. As to **claim 101**, Nelson teaches an apparatus wherein the appliance is biocompatible metal (**see column 10 lines 45-55**).

***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. Claims **52-55, 66-68, 70-78, 80, 81, 98 and 102-107** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 7,188,627).

23. **As to claims 52-81**, Neslon substantially discloses the method as claimed, see rejection above, including disclosing the method steps of providing an appliance **52 (see figures 7A and 7B; column 10 lines 10-20)** made of a biocompatible metal below a soft palate of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal (beneath the mucosal layer of the lateral and posterior walls of the oropharyngeal region) region of the human or animal (**see figures 7A and 7B; column 10 lines 45-55**), the appliance so provided having at least two laterally positioned elements substantially longitudinally spaced apart from each other to define an open space therebetween (**reference character 56 defines the open space**) and providing an opening force against the lateral walls of the oropharyngeal region.

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The method steps would have been obvious because they would have resulted from the use of the device of Nelson.

24. **As to claims 102 and 104-107**, Nelson substantially discloses the method as claimed, see rejection above, including disclosing the method steps of providing an appliance **52 (see figures 7A and 7B; column 10 lines 10-20)** comprising a continuous loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions; introducing the appliance into an oropharyngeal region (beneath the mucosal layer of the lateral and posterior walls of the oropharyngeal region); and releasing the appliance within the oropharyngeal region such that the elongated elements extends generally laterally across the posterior wall and the first and second end portions, bear against and provide an opening force against the lateral walls of the oropharyngeal region (**see column 6 lines 60-67; column 7 lines 1-10; and column 10 lines 10-20**).

The method steps would have been obvious because they would have resulted from the use of the device of Nelson.

25. **As to claim 103**, Nelson substantially discloses the method as claimed, see rejection above, including disclosing the method steps of providing an appliance that comprises a substantially C shaped configuration (**see figures 7A and 7B; the loop in figures 7A and 7B is defined as C-shaped structure**) with the first and second portions defining a gap therebetween when release within the oropharyngeal region (**reference character 56 defines the gap**).

The method steps would have been obvious because they would have resulted from the use of the device of Nelson.



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26. **As to claim 98**, Nelson substantially discloses the claimed invention; see rejection of claim 93 above, but does not disclose an appliance being expanded to a diameter greater than 32 mm in the deployed configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Nelson's invention by providing an appliance being expanded to a diameter greater than 32 mm in the deployed configuration in order to treat sleep apnea, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

#### ***Election/Restrictions***

27. Claims **95 and 96** remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 8<sup>th</sup>, 2004.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/  
Examiner, Art Unit 3772

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772